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JFCT-1-03 (CIP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): V. M. Chopdekar et al. :
SERIAL NO. : 10/734,460 : Examiner: Shahnam J. Sharareh
FILED : December 12, 2003 : Art Unit: 1617
FOR : OPIOID TANNATE COMPOSITIONS

PETITION FOR SUSPENSION OF ACTION BY THE OFFICE [37 C.F.R. § 1.103(a)]

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Applicants respectfully requests the Office to suspend action on this application for the reasons presented below. This Petition is accompanied by a showing of good and sufficient cause for the suspension of action as supported by Exhibits A - D attached hereto.

This Petition is also accompanied by a Credit Card Payment in the total amount of \$260, of which \$200 is due under 37 C.F.R. 1.17(g) in respect to this Petition and \$60 (small entity) is due in respect to the accompanying Petition for a one month extension of time

In the Office Action mailed June 6, 2006, claims 1-3 and 8-9 were rejected under 35 U.S.C. § 102 as being anticipated by British Patent 894,609 ("GB '609"). Claims 1-10 were also rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer US Patent 5,869,498 in view of GB'609. In order to establish patentability over the cited references, applicants have initiated a program to compare tannates of morphine and codeine prepared by the method described in GB'609 with the tannates of morphine and codeine prepared by the method described in the instant patent application. It is believed that there will be significant differences in the physical and chemical properties of the two types of tannates. However, applicants cannot respond to the rejections under 35 U.S.C. § 102/103(a) since applicants have not yet received permission from the Drug Enforcement Agency to acquire research quantities of morphine and codeine which are controlled substances

09/19/2006 TL0111 00000042 10734460

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200.00 OP

Exhibit A is a photocopy of a fax sent to the DEA on June 15, 2006 by Mary Ciamaga (Customer/Vendor Relations Manager for the Assignee: JFC Technologies) enclosing a Drug Code Change Request

Exhibit B is a photocopy of a letter by Ms. Ciamaga sent to the DEA on June 16, 2006 setting forth the reasons why the DEA should grant the assignee permission to purchase research quantities of codeine and morphine

A voice mail message was sent to the DEA on July 20, 2006 requesting an update on the status of the request to add codeine and morphine to the assignee's current category 2 registration.

On August 4, 2006, DEA Inspector Fred Kerr called the assignee for more information. A voice-mail message was left for Mr. Kerr indicating that the assignee's plant and laboratories would undergo its annual shutdown from August 5 through August 25 and that the requested information would be provided after the shutdown.

Exhibit C is a fax dated September 1, 2006 from DEA Inspector Kerr to Ms Ciamaga to provide the information requested in Paragraph 5 of the fax.

Exhibit D is a letter dated September 5, 2006 from Ms. Ciamaga to Mr. Kerr faxed on September 7, 2006 providing the requested further information and protocols regarding the need to purchase research quantities of codeine and morphine.

On September 18, 2006, a voice mail message was left with Mr. Kerr requesting a status update on the request to include codeine and morphine in the assignee's current drug registration.

It is respectfully submitted that the foregoing showing supports the granting of this Petition. If further information is required, please contact the undersigned at any time.

Respectfully submitted,


Jack Matalon
Attorney for Applicants
Reg. No. 22,441

Law Offices of Jack Matalon
32 Shelley Rd.
Springfield, NJ 07081-2529

Tel: (973) 467-5625
Fax: (973)-921-0817

EXHIBIT A

**JFC Technologies****"COMMON SENSE AND PLAIN DEALING"**

PO Box 669, 100 West Main Street, Bound Brook, NJ 08805, USA Tel (732) 469-7760 Fax (732) 469-3666
<http://www.jfctechnologies.com>

FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
Registration	Mary Ciamaga
COMPANY:	DATE:
D.E.A., Newark Division	6/15/2006 <i>prel.</i>
FAX NUMBER:	NO. OF PAGES INCLUDING COVER:
973-776-7055	3
PHONE NUMBER:	JFC PHONE NUMBER:
<i>973-776-888-356-1071</i>	732.469.7760 X 12
RE:	JFC FAX NUMBER:
Drug code addition	732.469.3666

☐ URGENT ☐ PLEASE REPLY VIA E-MAIL ☐ FOR REVIEW
☐ PLEASE REPLY VIA FAX

NOTES/COMMENTS:

Attached is a drug code change request. We wish to add drug codes 9050(codeine) and 9300(morphine) to our manufacturer registration (RJ0158318). These drugs are schedule 2 drugs and we are registered for schedule 2.

A protocol, which we will be submitting to the quota department, is also attached. *(for your information)*

Thank you,
Mary Ciamaga

"COMMON SENSE AND PLAIN DEALING"

EMERSON

EXHIBIT A

**DRUG CODE CHANGE REQUEST****INSTRUCTIONS**

An addition or deletion of a drug code on a current Drug Enforcement Administration (DEA) registration can be completed on this form. Complete the form below in its entirety. Failure to include the required information may result in a delay in the change requested. Once completed, sign the form, make a copy for your records, and mail or fax the form to your local Diversion Office. Visit the Offices and Directories section of the website to find your local office.

The only registration activities that require a drug code entry are the following:

Manufacturers - Schedule I, II, III, IIIN Only*
Distributors - Schedule I only
Researchers - Schedule I, II only

Importers - Schedule I thru V
Exporter - Schedule I thru V
Narcotic Treatment Programs

* Bulk Manufacturers must check the box next to the drug code for those "Basic Classes" of controlled substances that are proposed to be manufactured in bulk. Further information may be required for those substances.

Please refer to the drug code list and ensure that you are registered in the appropriate schedule for any drug code that you wish to handle.

DEA Registration Number: 2J0158318
Registered Name & Address: JPC Technologies, LLC
100 West Main Street
Bound Brook, NJ 08805
Tax Identification Number: 20-068-8610
Social Security Number: _____
Contact (Individual's Name): Mary Cianaga
Telephone Number: 732-469-7760ext.12

I wish to add the following drug code(s) to my registration:

9050	Bulk Also <input type="checkbox"/>	9300	Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>
	Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>

I wish to delete the following drug code(s) from my registration:

	Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>
	Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>		Bulk Also <input type="checkbox"/>

Signature: *Mary Cianaga* Date: 6/15/2006
(Signature is REQUIRED to process this form.)

EXHIBIT B

Airbill: 16662873754

**JFC Technologies****"COMMON SENSE AND PLAIN DEALING"**

June 16, 2006

Christine A. Samnerud, PhD, Chief
DEA - Office of Diversion Control
Drug & Chemical Evaluation Section (ODE)
(Procurement Quota Division)
Washington, DC 22301

Dear Ms. Samnerud:

JFC Technologies, LLC manufactures a line of Tannate products for the pharmaceutical (cough/cold) industry. We are applying for a patent on a new Tannate product (Hydrocodone Tannate). To obtain patent support information, our lab personnel will be attempting to prepare a Tannate salt of codeine and a Tannate salt of morphine. We would need to purchase Morphine sulfate and Codeine phosphate to prepare the Tannates, and so are applying for procurement quotas for Codeine and Morphine (CSA # 9050 and 9300). We need a quota of 50 grams for each item. We will be using these items for research purposes only and will not be distributing any products containing these drugs.

Also attached is the Drug Code Change request that we faxed to our local DEA office (Newark, NJ Division) adding these 2 drug codes to our manufacturing registration.

Potential Supplier: Spectrum Chemical, Gardena, CA 90248

If you need further information, please let us know.

Mary Ciarnaga
Customer/Vendor Relations Manager
732-469-7760 ext.12

Attachments: Procurement Quota Application for Codeine (CSA #9050)
Procurement Quota Application for Morphine (CSA # 9300)
Copy of Drug Code Change Request (faxed to Newark, NJ Division 6/15/06)

100 West Main Street & PO Box 669 & Bound Brook, New Jersey 08805 USA
Tel (732) 469-7760 & Fax (732) 469-3666
www.jfctechnologies.com

EXHIBIT B

U. S. Department of Justice
Drug Enforcement AdministrationAPPLICATION FOR PROCUREMENT QUOTA
FOR CONTROLLED SUBSTANCE

SEE INSTRUCTIONS ON REVERSE SIDE		No procurement quota may be issued unless a completed application form has been received, 31 CFR 1363.126.		OMB APPROVAL No. 1117-0008	
1. NAME OF BASIC CLASS DESIRED (Only one basic class per DEA-250) Cocaine		2. SCHEDULE NUMBER II		3. DEA DRUG CODE NUMBER 9050	
4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code) JFC Technologies, LLC 100 West Main Street (P.O. Box 669) Bound Brook, NJ 08805				5. YEAR FOR WHICH QUOTA IS REQUESTED 2006	
				6. DEA REGISTRATION NUMBER RJ 0158318	
7. NAME OF CONTACT PERSON Mary Ciannaga		8. TELEPHONE NO. (Include ext., if applicable) (732) 469-7760		9. FAX NUMBER 12 (732) 469-3666	

NOTE: All quantities are to be expressed in grams of anhydrous acid, base or alkaloid (not as salts).

10. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED 50 Grams
	2nd PRECEDING YEAR 0 Grams	1st PRECEDING YEAR 0 Grams	CURRENT YEAR 0 Grams	
11. PRODUCTION DATA	2nd PRECEDING YEAR	1st PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk controlled substance	0			0
b. In-process material				0
c. Contained in FINISHED Dosage Forms				0
TOTAL (a + b + c)	0	0	0	0
II. DISPOSITION / UTILIZATION				
a. Domestic				0
b. Exports				0
TOTAL (a + b)	0	0	0	0
III. ACQUISITION / PRODUCTION				
a. Domestic Sources				50
b. Importation				0
TOTAL (a + b)	0	0	0	50

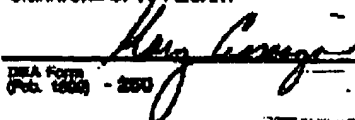
12. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE (S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA DRUG CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2nd PRECEDING YEAR	1st PRECEDING YEAR	CURRENT YEAR	

13. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS INTO DOSAGE FORMS, FURNISH THE FOLLOWING INFORMATION:

NAME OF DOSAGE FORM	SCHEDULE	AMOUNT USED FOR THIS PURPOSE		ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
		2nd PRECEDING YEAR	1st PRECEDING YEAR		

SIGNATURE OF APPLICANT



PRINT or TYPE NAME and TITLE of SIGNER

Mary Ciannaga DEA Coordinator

DATE

Jun 16, 2006

DEA Form
(Rev. 10-00) - 250

All previous editions are Obsolete.

EXHIBIT B

U. S. Department of Justice
Drug Enforcement AdministrationAPPLICATION FOR PROCUREMENT QUOTA
FOR CONTROLLED SUBSTANCE

SEE INSTRUCTIONS ON REVERSE SIDE		No procurement quota may be issued unless a completed application form has been received, 31 CFR 1305.12(b).		OMB APPROVAL No. 1117-0008	
1. NAME OF BASIC CLASS DESIRED (Only one basic class per DEA-250)		2. SCHEDULE NUMBER		3. DEA DRUG CODE NUMBER	
Morphine		II		9300	
4. NAME AND ADDRESS OF REGISTRANT (Include No., Street, City, State and ZIP Code)				5. YEAR FOR WHICH QUOTA IS REQUESTED	
JFC Technologies, LLC 100 West Main Street (P.O. Box 669) Bound Brook, NJ 08805				2006	
7. NAME OF CONTACT PERSON				8. DE A REGISTRATION NUMBER	
Mary Ciannaga				RJ 0158318	
9. TELEPHONE NO. (Include ext., if applicable)				9. FAX NUMBER	
(732) 469-7760				12 (732) 469-3666	

NOTE: All quantities are to be expressed in grams of anhydrous salt, base or alkaloid (not as salts).

10. QUOTA HISTORY	QUOTAS PREVIOUSLY ISSUED BY DEA			QUOTA REQUESTED
	2nd PRECEDING YEAR	1st PRECEDING YEAR	CURRENT YEAR	
	0 Grams	0 Grams	0 Grams	50 Grams
11. PRODUCTION DATA	2nd PRECEDING YEAR	1st PRECEDING YEAR	ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
I. INVENTORY AS OF DEC. 31				
a. Bulk controlled substance	0			0
b. In-process material				0
c. Contained in FINISHED Dosage Forms				0
TOTAL (a + b + c)	0	0	0	0
II. DISPOSITION/UTILIZATION				
a. Domestic				0
b. Exports				0
TOTAL (a + b)	0	0	0	0
III. ACQUISITION/PRODUCTION				
a. Domestic Sources				50
b. Importation				0
TOTAL (a + b)	0	0	0	50

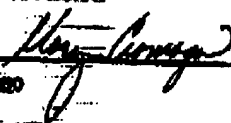
12. IF THE PURPOSE IS TO MANUFACTURE ANOTHER SUBSTANCE (S), FURNISH THE FOLLOWING INFORMATION:

NAME OF NEW SUBSTANCE	DEA DRUG CODE NUMBER	AMOUNT USED FOR THIS PURPOSE			% YIELD (Historical)
		2nd PRECEDING YEAR	1st PRECEDING YEAR	CURRENT YEAR	

13. IF THE PURPOSE IS TO MANUFACTURE THE BASIC CLASS INTO DOSAGE FORMS, FURNISH THE FOLLOWING INFORMATION:

NAME OF DOSAGE FORM	SCHEDULE	AMOUNT USED FOR THIS PURPOSE			ESTIMATE FOR CURRENT YEAR	ESTIMATE FOR YEAR FOR WHICH QUOTA IS REQUESTED
		2nd PRECEDING YEAR	1st PRECEDING YEAR			

SIGNATURE OF APPLICANT



PRINT or TYPE NAME and TITLE of SIGNER

Mary Ciannaga DEA Coordinator

DATE

Jun 16, 2006

DEA Form
(Feb. 1999) - 250

All previous actions are OBSOLETE.

EXHIBIT C

Department of Justice
Drug Enforcement Administration

FAX TRANSMITTAL SHEET for UNCLASSIFIED INFORMATION ONLY

<div>1</div>	09 / 01 / 2006 Date	<div>2</div>	Number of pages being transmitted (including this transmittal sheet)	1
<div>3</div>				
TO: FAX#: 732-469-2466				
NAME: Mary Giamber				
PHONE: 732-469-7760 OFFICE/ORG: JTC TECHNOLOGIES				
<div>4</div>				
FROM: FAX#: 973-776-1186				
NAME: Diversion Investigator Fred Kerr				
PHONE: 973-776-1173				
OFFICE/ORG: New Jersey Division				
<div>5</div>				
Additional Comments				

On 09-01-2006, I requested that your firm provide the protocols, quantity on hand per month and per year, storage arrangements, and recordkeeping procedures for drug codes 9050 and 9300 that you requested be added to your firm's Manufacturer's registration, DEA 68J0158319. To date, I have not received this information. Please respond by providing all the requested information upon receipt of this faxmail.

"NOTICE: This is an official government communication that may contain privileged or sensitive information intended solely for the individual or entity to which it is addressed. Any review, retransmission, dissemination or other use or action taken upon this information by persons or entities other than the intended recipient is prohibited. If you are not the intended recipient or believe you received this communication in error, please contact the sender immediately."

Note: If you have any problems with this transmission (incorrect number of pages/poor quality), call the sender and request retransmission.

DEA Form 801 Fax Transmittal Sheet for Unclassified Information Only
(January 2004)

EXHIBIT D

3

**JFC Technologies****"COMMON SENSE AND PLAIN DEALING"**

September 7, 2006

Protocol for Codeine Tannate:

To obtain patent support information, we will be attempting to prepare a Tannate salt of codeine. We would need to use Codeine sulfate to prepare the Tannate.

Codeine Sulfate = 25 grams

Note: Patent example uses codeine sulfate as reactant and not as a base.

(1) Replicate patent example :

12 grams of codeine sulfate + 120cc of methyl alcohol + 30 cc of 1 N NaOH

To slurry produced from above, add 12 grams of tannic acid in 120cc of methyl alcohol.

Yield = 9 grams of Codeine Tannate

(2) JFC Technologies procedure:

Convert 12 grams of codeine sulfate to codeine base by reaction with dilute NaOH.

The yield of codeine base (95%) = $\frac{12 \times 598.72}{750.86} \times 0.95 = 9.1$ grams of codeine base

Use 1.1 grams of codeine base for assay and characterization.

8 grams of base for synthesizing Tannate.

React 8 grams of codeine base with 9.1 grams of tannic acid (5:1 mole ratio)

Yield = 16.25 grams (at 95% yield) of Codeine Tannate.

(3) Characterize Codeine Tannate from steps (1) and (2) above by % base assay, FTIR and reactivity test.

100 West Main Street & PO Box 669 & Bound Brook, New Jersey 08805 USA
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EXHIBIT D

2

**JFC Technologies****"COMMON SENSE AND PLAIN DEALING"**

September 7, 2006

Protocol for Morphine Tannate:

To obtain patent support information, we will be attempting to prepare a Tannate salt of morphine. We would need to use Morphine sulfate to prepare the Tannate.

Morphine Sulfate = 25 grams

1 gram for assay. 24 grams will be converted to morphine base by reaction with dilute NaOH.

The yield of morphine base (95%) = $\frac{24 \times 570.66}{758.33} \times 0.95 = 17.16$ grams of morphine base

2.16 grams for assay/retain sample.

(1) Replicate patent example :

To 7 grams of morphine base + 70 cc of Isopropyl Alcohol, add 10.5 grams of tannic acid in 35cc of warm alcohol.

Yield = 13.5 grams of Morphine Tannate

(2) JFC Technologies procedure:

React 7 grams of morphine base (0.02453 moles) 8.3 grams of tannic acid

Yield = 14.54 grams (at 95% yield) of Morphine Tannate.

Characterize Morphine Tannate from steps (1) and (2) above by % base assay, FTIR and reactivity test.

100 West Main Street ▲ PO Box 669 ▲ Bound Brook, New Jersey 08805 USA
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EXHIBIT D

page 1 of 3

**JFC Technologies****"COMMON SENSE AND PLAIN DEALING"**

September 5, 2006 Revised 9/7/06

To: Mr. Fred Kerr
Diversion Investigator
Newark Division
Drug Enforcement Administration


Fax #: (973)776-1166

Dear Mr. Kerr,

This is in response to your fax of 09/01/06 and phone call of 08/04/06 regarding our drug code addition request. We apologize for not getting the information to you sooner, but JFC was on a production shutdown from Aug. 5th through Aug. 28th and we were unable to get the information needed.

1. **Protocols:** Attached.
2. **Quantity on Hand.** We anticipate ordering 25 grams of Codeine (CSA 9050) and Morphine (CSA 9300) initially. If we need to repeat the experiments, we will be ordering an additional 25 grams of each item. We will be using the items for R&D purposes.
Therefore, we expect to have 25 grams of each item on hand the first month of use, then 25 to 50 grams per month till such time as we have a DEA sanctioned disposal. (Approximately 1 to 2 years on hand).
3. **Security.** The materials will be stored in a Bullion UL TL 30 safe, model BU352420, manufactured by ISM, purchased from Wilson Safe.
4. **Recordkeeping procedures:** We will maintain records as per part 1304 of the regulations.

A copy of our company SOP on DEA materials is also attached. Faxed 9/5/06


Mary Chappin
Customer/Vendor Relations Manager
(732)469-7760 ext.12

Attachments: Protocols on codeine and morphine
JFC SOP-CO-015 Faxed 9/5/06

FAXED

100 West Main Street ▲ PO Box 669 ▲ Bound Brook, New Jersey 08805 USA
Tel (732) 469-7760 ▲ Fax (732) 469-3666
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